NOIDA INSTITUTE OF ENGINEERING AND TECHNOLOGY

(PHARMACY INSTITUTE), GREATER NOIDA, U.P. 201306

A Report on

Advanced Clinical Trial Design and Management

Noida Institute of Engineering and Technology (Pharmacy Institute) initiated a short-term certificate course in **"Advanced Clinical Trial Design and Management"** from **24th April 2024 to 28th April 2024**. 70 students of the Bachelor of Pharmacy have participated in the course. This 5-day certification course on Clinical Trial Design and Management provided participants with in-depth knowledge of modern clinical trial methodologies, regulatory frameworks, and innovative management strategies. Designed for clinical research professionals, the course covered advanced trial designs, risk-based monitoring, and the integration of digital technologies to enhance trial efficiency and data integrity.

The program began with an inaugural session, in which **Dr. Avijit Mazumder** (Director, NIET Pharmacy Institute) highlighted an **overview of clinical trial designs**, including adaptive, Bayesian, and decentralized models. Participants explored their applications in improving flexibility, efficiency, and patient outcomes. On the second day, **Dr. Manju Sharma,** Professor, Jamia Hamdard, focused on regulatory compliance, where attendees examined FDA, EMA, and ICH-GCP guidelines, along with ethical considerations in global trials. On Day 3, **Dr. Pradeep Mishra,** Professor, GLA Mathura, covered risk-based monitoring and data integrity, equipping participants with strategies to ensure high-quality data collection and analysis. **Dr. Gunjan Sharma,** Associate Professor, DIPSAR, covered digital transformation in clinical research was explored, real-world evidence (RWE), artificial intelligence, and wearable technologies in patient monitoring on day 04 session. The final day, **Dr. Saumya Das,** Professor, NIET (Pharmacy Institute), addressed trial management challenges, such as patient recruitment, site selection, and post-market surveillance. Participants engaged in case studies and a capstone project, applying their knowledge to real-world scenarios. Upon completion, they received a certification, validating their expertise in advanced clinical trial design and management.